

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF PUERTO RICO

MARIA DE LOS A. ROSA,  
et al.,

Plaintiffs,

v.

MEDTRONIC MINIMED, INC.,  
et al.,

Defendants.

CIVIL NO. 03-2399 (RLA)

**ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

Defendant, Medtronic Minimed, Inc. ("MiniMed"), has moved the Court to enter summary judgment on its behalf and to dismiss the claims asserted against it in these proceedings.

In support of its initial summary judgment request, MiniMed alleges: (1) that Angel's DKA episode was due exclusively to his failure to properly monitor his blood glucose levels and not to the connection of the insulin pump and (2) that MiniMed had no duty to warn plaintiff regarding the risk of DKA and even if it did, defendant discharged any such duty to warn. Subsequently, defendant further alleged that it was not liable for Dr. Pijem's acts or omissions because she was an independent contractor.

The Court having reviewed the memoranda filed by the parties as well as the evidence submitted in support thereof finds that issues of material fact preclude summary judgment at this stage of the proceedings.

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**PROCEDURAL BACKGROUND**

This action was instituted by the parents of Angel J. Diaz-Rosa ("Angel") on their own behalf and on behalf of their then minor son<sup>1</sup> for alleged damages resulting from Angel's three-day hospitalization for Diabetic Ketoacidosis ("DKA") in 2001. According to plaintiffs, the DKA and subsequent hospitalization were purportedly due to an insulin pump used by Angel which was manufactured by MiniMed and installed by Dr. Gladys Gonzalez de Pijem ("Dr. Pijem"). The complaint, labeled as one for "medical malpractice", was based on our diversity jurisdiction and named MiniMed as well as Dr. Pijem as defendants. Subsequently, plaintiffs voluntarily dismissed the claims asserted against Dr. Pijem in order to preserve the required diversity of citizenship between the parties.<sup>2</sup> Accordingly, only the causes of action asserted against Minimed remain pending.

**SUMMARY JUDGMENT STANDARD**

Rule 56(c) Fed. R. Civ. P., which sets forth the standard for ruling on summary judgment motions, in pertinent part provides that they shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as

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<sup>1</sup> Angel became of legal age in April 2005. See Motion Requesting Permission to Amend Complaint (docket No. 34) ¶ 8.

<sup>2</sup> See Partial Judgment issued on August 13, 2004 (docket No. 17).

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a matter of law." Sands v. Ridefilm Corp., 212 F.3d 657, 660-61 (1<sup>st</sup> Cir. 2000); Barreto-Rivera v. Medina-Vargas, 168 F.3d 42, 45 (1<sup>st</sup> Cir. 1999). The party seeking summary judgment must first demonstrate the absence of a genuine issue of material fact in the record. DeNovellis v. Shalala, 124 F.3d 298, 306 (1<sup>st</sup> Cir. 1997). A genuine issue exists if there is sufficient evidence supporting the claimed factual disputes to require a trial. Morris v. Gov't Dev. Bank of Puerto Rico, 27 F.3d 746, 748 (1<sup>st</sup> Cir. 1994); LeBlanc v. Great Am. Ins. Co., 6 F.3d 836, 841 (1<sup>st</sup> Cir. 1993), *cert. denied*, 511 U.S. 1018, 114 S.Ct. 1398, 128 L.Ed.2d 72 (1994). A fact is material if it might affect the outcome of a lawsuit under the governing law. Morrissey v. Boston Five Cents Sav. Bank, 54 F.3d 27, 31 (1<sup>st</sup> Cir. 1995).

"In ruling on a motion for summary judgment, the court must view 'the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor.'" Poulis-Minott v. Smith, 388 F.3d 354, 361 (1<sup>st</sup> Cir. 2004) (*citing* Barbour v. Dynamics Research Corp., 63 F.3d 32, 36 (1<sup>st</sup> Cir. 1995)).

Credibility issues fall outside the scope of summary judgment. "'Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.'" Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150, 120 S.Ct. 2097, 147 L.Ed.2d 105 (2000) (*citing* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505,

91 L.Ed.2d 202 (1986)). See also, Dominquez-Cruz v. Suttle Caribe, Inc., 202 F.3d 424, 432 (1<sup>st</sup> Cir. 2000) ("court should not engage in credibility assessments."); Simas v. First Citizens' Fed. Credit Union, 170 F.3d 37, 49 (1<sup>st</sup> Cir. 1999) ("credibility determinations are for the factfinder at trial, not for the court at summary judgment."); Perez-Trujillo v. Volvo Car Corp., 137 F.3d 50, 54 (1<sup>st</sup> Cir. 1998) (credibility issues not proper on summary judgment); Molina Quintero v. Caribe G.E. Power Breakers, Inc., 234 F.Supp.2d 108, 113 (D.P.R. 2002). "There is no room for credibility determinations, no room for the measured weighing of conflicting evidence such as the trial process entails, and no room for the judge to superimpose his own ideas of probability and likelihood. In fact, only if the record, viewed in this manner and without regard to credibility determinations, reveals no genuine issue as to any material fact may the court enter summary judgment." Cruz-Baez v. Negron-Irizarry, 360 F.Supp.2d 326, 332 (D.P.R. 2005) (internal citations, brackets and quotation marks omitted).

#### FACTUAL BACKGROUND

Angel was diagnosed with Insulin Dependent Diabetes ("IDDM" or "Type I Diabetes") when he was between seven and nine years old. He was treated by Dr. Miriam N. Alicea, a pediatric endocrinologist, until he turned 18 years old.

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3 IDDM is a syndrome characterized by hyperglycemia (high blood  
4 glucose levels) resulting from absolute or relative impairment in  
5 insulin secretion and/or insulin action.

6 DKA is a metabolic disorder that occurs when blood glucose levels  
7 are high (hyperglycemia) and insulin levels are low.

8 In Type I Diabetes patients, DKA is commonly precipitated by a  
9 lapse in insulin treatment or by an acute infection, trauma, or  
10 infraction that makes the usual insulin treatment inadequate.

11 Education of diabetes patients is essential, among other  
12 reasons, for the effectiveness of prescribed therapy and to recognize  
13 indications for seeking medical attention. Blood glucose levels can  
14 be tested at home with easy to use home analyzers, using a drop of  
15 finger tip blood.

16 Type I Diabetes pediatric patients and their parents are taught  
17 to test their blood glucose at least four times a day. Type I  
18 Diabetes pediatric patients and their parents are educated about the  
19 risk of DKA and how to identify and respond to it when they are first  
20 diagnosed with the disease.

21 Type I Diabetes patients are at risk of DKA regardless of the  
22 method they use to administer insulin.

23 Dr. Alicea filled out a Prescription and Medical Necessity form  
24 used by plaintiffs to purchase a MiniMed 508 Insulin Pump  
25 manufactured by defendant.  
26

Insulin pumps or "continuous subcutaneous insulin infusion" are defined as:

A mode of intensive insulin treatment in patients with Type I DM [which] involves a small battery-powered infusion pump that provides a continuous subcutaneous infusion of rapid-acting insulin through a small needle, usually inserted in the abdominal wall. The pump is programmed to infuse a selected basal rate of insulin, supplemented by manually triggered or programmed increased rates before each meal. The patient measures glucose levels several times a day to adjust the dosage.

Mark H. Beers, M.D. & Robert Berkow, M.D., The Merck Manual of Diagnosis and Therapy (17<sup>th</sup> ed. 1999) p. 173.

Plaintiff purchased a MiniMed 508 Insulin Pump directly from defendant via the internet. The device was shipped to plaintiffs on November 21, 2000 together with a User's Guide in English.

On February 16, 2001, Dr. Pijem attended a seminar entitled "*Intensive Diabetes Management: Utilizing Insulin Pump Therapy*". Dr. Pijem was at that time, and still is, a board-certified Pediatric Endocrinologist and the Director of the Pediatric Endocrinology Department of the University of Puerto Rico School of Medicine.

At the aforementioned seminar, Dr. Pijem attended lectures and was provided with written materials. Among those materials was a manual entitled "*Pumping Protocol: A Physician's Guide to Insulin*

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*Pump Therapy Initiation*", authored by Dr. Bruce W. Bode pursuant to an educational grant from MiniMed, Inc. ("the Pumping Protocol").

The Pumping Protocol was directed both at physicians beginning to prescribe pump therapy as well as those with extensive experience in the matter. MiniMed also provided Dr. Pijem with a MiniMed 508 Pump User's Guide.

In mid March 2001 Dr. Pijem connected Angel to the MiniMed 508 pump.

On March 31, 2001, Angel was taken to the emergency room at Hospital Interamericano de Medicina Avanzada ("HIMA") in Caguas. At that time the pump was disconnected and it showed that its cannula<sup>3</sup> was bent which did not allow for the insulin to flow as expected.

On April 1, 2001, Angel was transferred to the San Jorge Children's Hospital and admitted into its Intensive Care Unit ("ICU") with a diagnosis of DKA and moderate dehydration. On April 2, 2001, Angel's DKA had resolved and he was transferred from the ICU to the ward.

According to Dr. Julio Albino, plaintiffs' expert witness, Angel could have avoided DKA had he checked his blood glucose levels four to six times a day.

Dr. Albino indicated that had Angel experienced high blood glucose levels while on the pump, he could have taken off the pump;

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<sup>3</sup> "[A] tube for insertion into a duct or cavity." Dorland's Illustrated Medical Dictionary (W.B. Saunders Co. 25<sup>th</sup> ed. 1974).

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2  
3 taken an injection of regular insulin by syringe to lower his blood  
4 glucose levels and contacted a physician for advise.

5 Dr. Albino further noted that Dr. Alicea had the necessary  
6 knowledge to lower Angel's blood glucose levels if they were high  
7 while Angel was using the MiniMed 508 pump.

8 Plaintiffs did not contact Dr. Alicea to report high glucose  
9 levels during March 2001 when Angel was reportedly using the MiniMed  
10 508 pump or when his bout of DKA began even though they had her  
11 office and home telephone number.

12 Angel was a camper in diabetes summer camps overseen by Dr.  
13 Miriam N. Alicea. One of the purposes of these camps was to teach  
14 campers the fundamentals of diabetes care as well as learn good  
15 health habits such as proper diet, blood glucose monitoring, insulin  
16 dose adjustment and exercise. Angel learned about the pump through a  
17 camp counselor.

18 Dr. Alicea teaches her patients to test their urine for ketones  
19 whenever their blood glucose levels exceed 240 mg/dl.

20 According to Dr. Alicea, given the years as a diabetes patient  
21 and attendance at diabetes camp, in March of 2001 Angel knew or  
22 should have known that two or more blood glucose level readings above  
23 240 milligrams per deciliter indicate a risk of ketoacidosis and that  
24 he should check for ketones.

25 Dr. Alicea filled out the prescription form for the pump but was  
26 not familiar with the device. Dr. Alicea acknowledged that she never



managed a patient with a pump because she did not have any training in this technology.

### THE CLAIMS

Inasmuch as this is an action based on diversity of citizenship Puerto Rico substantive law is used to determine liability. Correa v. Cruisers, 298 F.3d 13, 22 (1<sup>st</sup> Cir. 2002).

Ascertaining which are the specific claims asserted in these proceedings in order to properly address their viability has proved a difficult task. Even though the complaint only makes mention of negligence claims, in their memoranda plaintiffs have also included arguments pointing to defendant's alleged responsibility for breach of its duties under products liability doctrines.

Upon reviewing the only complaint on file we must reach the inescapable conclusion that the claims asserted therein are predicated exclusively on the negligent acts or omissions of Dr. Pijem. It is noteworthy that the complaint explicitly labeled the action as a "Medical Malpractice" suit. In this vein, the pleading specifically avers that Dr. Pijem did not ensure that the "device was well connected, adequately managed and was functioning properly",<sup>4</sup> and also failed to evaluate, treat and/or refer Angel to another physician or for testing in light of his complaints.<sup>5</sup> Even though plaintiffs were granted leave to amend their complaint to include

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<sup>4</sup> Complaint (docket No. 1) ¶ 19.

<sup>5</sup> Id. ¶¶ 21-22.

allegations regarding malfunction of the equipment due to an alleged failure in the alarm system the amended pleading was never filed.<sup>6</sup>

In sum, in the outstanding pleading MiniMed is charged only with vicarious liability premised on the conduct of Dr. Pijem, its purported local representative. Plaintiffs specifically allege that the damages complained of "are [the] direct cause of the negligence of MiniMed, and their representative Dr. Gonzalez de Pijem."<sup>7</sup>

In pertinent part, the pleading describes MiniMed's negligence as follows:

¶32. MiniMed (sic) representative was not capable of effectively and safely performing the important task of installing the insulin pump, which is a life depending device... [despite] her lack of training and education and even without the necessary skills, MiniMed authorized her to do it. In this particular case, her mishandling, wrongful... connection of the device and mistreatment (sic) of the minor resulted in a near death situation and its consequences for which MiniMed and their representative should respond.

¶33. Such disregard by defendants of the health of the minor and by referring the minor to obtain the medical

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<sup>6</sup> See Motion Requesting Permission to Amend Complaint, filed on July 2, 2005 (docket No. 34) and Order granting the request, issued on July 21, 2005 (docket No. 35).

<sup>7</sup> Complaint (docket No. 1) ¶ 31.

services of connecting a life depending device without the proper training and knowledge was the proximate cause of the critical medical condition the minor underwent....

No failure to warn or other product liability claim aimed directly at defendant's acts or omissions even remotely appears pled in the complaint. Rather, plaintiffs charge Dr. Pijem under the negligence doctrine of informed consent whereby she allegedly failed in her duty to fully disclose relevant information regarding the MiniMed pump as well as the device's known risks and advantages. In pertinent part, the pleading avers that Dr. Pijem "never advised the [plaintiffs] of any consequences, possible malfunctions or situations to be alert, which constituted a violation of the informed consent obligation".<sup>8</sup>

Having clarified the precise nature of the claims asserted in these proceedings we now proceed to determine whether or not summary judgment is in order.

#### **Apparent Authority**

Defendant argues that it should not be held accountable for Dr. Pijem's purported negligent acts or omissions inasmuch as she was not its employee but rather an independent contractor. Plaintiffs, on the other hand, aver that based on defendant's representations they were led to believe that Dr. Pijem was MiniMed's agent in Puerto Rico.

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<sup>8</sup> Complaint (docket No. 1) ¶ 18.

Apparent authority may subject a principal to liability when a third party reasonably believes that an actor has authority to bind that principal based on the principal's representations. In order to prove apparent authority plaintiffs must establish that they relied in good faith in the conduct before them which conduct would lead a reasonable person to believe that a principal-agent relationship indeed existed. Vega v. Admin. Servs. Medicos, 117 D.P.R. 138, 147 (1986). This doctrine, which is based on equitable principles, provides that a principal is estopped from disclaiming an agency relationship before a third party where it has expressly or implicitly led the third party to believe that such a relationship exists. Berrios Pagan v. Univ. of P.R., 116 D.P.R. 88, 102 n.2 (1986).

According to plaintiffs, upon purchasing the pump MiniMed referred them to Dr. Pijem, their "representative".<sup>9</sup> Angel's mother, Mrs. Rosa, further indicated that Dr. Pijem regretted having to spend time taking the training and connecting the pumps because she was only going to be paid \$200.00 which did not compensate for the time this process entailed given her years of professional preparation. Plaintiffs had never met Dr. Pijem prior thereto.

Absent evidence contradicting plaintiffs' assertion regarding the alleged representations made by MiniMed with respect to its

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<sup>9</sup> Maria de los A. Rosa depo. Tr. 107.

relationship with Dr. Pijem, summary judgment on this issue in defendant's favor is not viable.<sup>10</sup>

### Causal Relationship

Defendant contends that the exclusive proximate cause of Angel's DKA was plaintiffs' failure to take ordinary care measures expected of a Type I Diabetes pediatric patient to manage his glucose levels and avoid DKA. According to movant, these measures include testing urine for ketones whenever blood glucose levels exceed certain values and seeking medical help prior to developing DKA. Specifically, defendant avers that Angel should have closely monitored his blood glucose levels and taken the necessary steps to remedy the situation such as disconnecting the insulin pump, switching to an injection of regular insulin and seeking immediate medical attention.

In support thereof, defendant notes that Angel had been diagnosed with Type I Diabetes for over six years prior to the DKA incident and had been under the care of Dr. Alicea since 1995. Dr. Alicea testified that she had educated Angel and his parents in glucose monitoring both at her office as well as during camps organized by her.

Art. 1802 of the Puerto Rico Civil Code, 31 P.R. Laws Ann. § 5141 (1990), governs tort liability in Puerto Rico. According to this provision, a person is liable for damages resulting from his/her

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<sup>10</sup> Given the fact that plaintiffs are pursuing liability under the apparent authority doctrine there is no need for us to address defendant's learned intermediary defense.

negligent acts or omissions. In order to prevail, plaintiff must establish: (1) a negligent act or omission, (2) damages, and (3) a causal relationship between them. Irvine v. Murad Skin Research Laboratories, Inc., 194 F.3d 313, 321-322 (1<sup>st</sup> Cir. 1999); De-Jesus-Adorno v. Browning Ferris Indus. of P.R., Inc., 160 F.3d 839, 842 (1<sup>st</sup> Cir. 1998); Marshall v. Perez Arzuaga, 828 F.2d 845, 847 (1<sup>st</sup> Cir. 1987); Pons Anca v. Engebretson, 160 D.P.R. 347 (2003); Montalvo v. Cruz, 144 D.P.R. 748, 758 (1998); Toro-Aponte v. E.L.A., 142 D.P.R. 464, 473 (1997).

Plaintiff must establish that the conduct at issue was the factor which most probably caused the damages and the cause and effect relationship between both. Soto Cabral v. E.L.A., 138 D.P.R. 298, 316 (1995). The mere fact that injuries or damages ensue is not grounds for liability under art. 1802 for that would entail absolute liability. Defendants will be liable only for those reasonably foreseeable consequences to their conduct. De-Jesus-Adorno, 160 F.3d at 842; Pons Anca, 2003 TSPR 150, 2003 WL 22399583, \*3-3; Montalvo, 144 D.P.R. at 755; Toro-Aponte, 142 D.P.R. at 473; Ocasio Juarbe v. Eastern Airlines, Inc., 125 D.P.R. 410, 418 (1990) *Official translation reproduced in full in* 902 F.2d 117 (1<sup>st</sup> Cir. 1990); Jimenez v. Pelegrina Espinet, 112 D.P.R. 700, 704, 1982 WL 210615 (1982); Pacheco v. A.F.F., 112 D.P.R. 296, 300 (1982).

Further, this is a comparative negligence jurisdiction. Art. 1802 specifically provides that the negligence of a plaintiff will

not bar a tort-based claim but rather that the relief awarded shall be reduced proportionate to the degree of plaintiff's negligence. Pons, 160 D.P.R. at 362.

While the record reveals that both Angel and his parents were indeed instructed on how to monitor and manage his glucose levels well before the DKA incident as defendant contends, there is also admissible evidence on record pointing to the fact that Angel's prior experience was with long-acting insulin via syringes and not with the short-acting insulin to be dispensed by the pump. Further, according to Dr. Rebecca Saenz, an endocrinologist who treated Angel while hospitalized for DKA at the San Jorge Hospital, when a pump is first connected the patient is initially started with saline for two or three days to ensure that he can handle it as well as to allow an opportunity for the patient to get acquainted with the pump.<sup>11</sup> There is no evidence that this procedure was followed in Angel's case.

The mother indicated that she was very nervous because of Angel's unusually high glucose levels for which reason she consulted Dr. Pijem daily. Mrs. Rosa stated that she called the physician every day after the connection because her son's glucose levels had risen over 200 which had never happened before. Mrs. Rosa testified that the physician responded that there was no problem, that it was due to the changes due to the new machine and the different type of insulin used.

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<sup>11</sup> Dr. Saenz depo. Tr. 49.

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3 According to Mrs. Rosa, by the third or fourth day Dr. Pijem  
4 responded in an annoyed manner at Mrs. Rosa, insisting as she had  
5 previously indicated, that the situation was normal. Angel's mother  
6 stated that she called for four or five days after the pump was  
7 connected. Thereafter she could not call because Dr. Pijem went on a  
8 trip.

9 Mrs. Rosa explained that she did not call Dr. Alicea during this  
10 period of time because the physician had previously indicated that  
11 even though she would continue to be Angel's physician she had no  
12 knowledge regarding the pump and therefore, could not assist in  
13 matters related to it. Angel's mother explained that she understood  
14 that Dr. Pijem was in charge of all matters related to the pump given  
15 the fact that she had installed the equipment. Further, given Dr.  
16 Pijem's position as Director of Endocrinology at the University of  
17 Puerto Rico School of Medicine they were confident in following her  
18 advise.

19 The record does reflect that plaintiffs took prompt and, what  
20 seemed to them at the time, a reasonable recourse in responding to  
21 Angel's unusually high glucose levels. Mrs. Rosa explained how she  
22 alerted Dr. Pijem of the abnormal situation as early as the day  
23 following the pump installation and for a number of days thereafter  
24 only to be appeased by the physician who suggested that it was part  
25 of Angel's adaptation process to the pump. As plaintiffs noted, Dr.  
26 Pijem's qualifications were outstanding and there was no apparent



reason for them to doubt her professional judgment particularly, when she was the person who had installed the pump. Further, Dr. Alicea, Angel's endocrinologist, acknowledged that she had alerted plaintiffs to the fact that she could not and would not monitor the pump because she lacked any training regarding the equipment.

Hence, we find that there are material facts in controversy regarding the proximate cause of Angel's DKA. Contrary to defendant's position that the damages claimed in the complaint ensued exclusively due to Angel's failure to adequately monitor his glucose levels<sup>12</sup> and take the necessary measures in response thereof, there is ample evidence to support plaintiffs' theory that their acts or omissions resulted instead from plaintiffs' reliance on Dr. Pijem's purportedly erroneous advise.

### Informed Consent

As previously noted, in their complaint plaintiffs adduced a claim based on the alleged lack of informed consent.<sup>13</sup>

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<sup>12</sup> Defendant suggests that because Angel's notations of his glucose levels after March 2001 are not available we should draw an inference that he never tested for glucose during this period. However, Angel testified that he threw those notations away and we see no grounds for the negative inference suggested by defendant on the record currently before us.

<sup>13</sup> Given the nature of the claims asserted in the pleadings, there is no need for us to entertain defendant's arguments regarding MiniMed's duty to warn customers regarding hazards posed by the use of its products under strict liability principles inasmuch as no such cause of action has been alleged. See *i.e.*, Cruz-Vargas v. R.J. Reynolds Tobacco Co., 348 F.3d 271 (1<sup>st</sup> Cir. 2003) (products liability claim based on failure to warn doctrine).

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"The right of every patient to self-determination, that is, to freely decide what can be done with his or her body, is protected by the courts. As a rule, it implies the prior informed consent by the patient... This does not mean that physicians are obliged to give their patients a complete course in medicine, but it does oblige them to keep them adequately informed about the nature of the treatment, the risks and complications involved, and the benefits expected." Sepulveda v. Barreto, 1994 P.R. Offic. Trans. 908,876, 137 D.P.R. 735 (1994).

"[A] patient suing for lack of informed consent does not need to prove a separate negligent act, other than the lack of informed consent." Cruz Aviles v. Bella Vista Hosp., Inc., 112 F.Supp.2d 200, 202 (D.P.R. 2000). He must, however, present evidence of damages as well as a causal relationship between the failure to provide adequate information and the damages. *Id. See also*, Santiago v. Hosp. Cayetano Coll y Toste, 260 F.Supp.2d 373, 385 (D.P.R. 2003).

Apparently, Angel's connection was either the first or one of the first occasions in which Dr. Pijem installed an insulin pump. According to Angel's mother, the physician did not appear proficient at what she was doing and kept referring back to some written instructions.

Mrs. Rosa testified in her deposition that apart from having to change the cannula Dr. Pijem did not give them any explanations

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regarding the pump.<sup>14</sup> However, Dr. Gildred Colon, defendant's expert witness, opined in her report that even though a written informed consent document was not warranted prior to initiating pump therapy, she did acknowledge that "[v]erbal and/or written documentation of pros and cons of pump therapy, complications, troubleshooting etc., like in a manufacturer's manual of safe use" was necessary.

The fact that there was printed material accompanying the pump purchased by plaintiffs which explained the risks involved with its use as well as the steps to be taken in case of a problem is not conclusive for purposes of the lack of informed consent claim. It appears that this information was written only in English which plaintiffs did not understand. In her deposition Dr. Pijem conceded as much.

Q. Now, during the course of our meetings with Angel Díaz and his family, did Angel tell you that he couldn't read the user's guide because it was in English?

A. I had the feeling that they didn't understand English too well, but I can't remember whether he came out and said so or his family said, but I had the feeling he couldn't... his knowledge was not very good.

Dr. Pijem depo. Tr. 84.

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<sup>14</sup> Maria de los A. Rosa depo. Tr. 108.

Angel's mother also testified in this regard. "I don't know English and [my husband] understands a little".<sup>15</sup> Angel's father only had limited training in the armed forces and had difficulty communicating in English. In his deposition he indicated that he "had quite a problem with [English]."<sup>16</sup>

In sum, based on the record before us, whether or not Dr. Pijem had a duty to provide plaintiffs with particular information regarding the benefits of the pump and of any associated risks and complications incidental thereto as well whether or not she did indeed provide such information is a matter to be decided at trial.

#### Other Claims

In response to defendant's petition for dismissal, plaintiffs further argue that: (1) the pump was defective because its alarm system was not triggered despite its alleged malfunction and (2) MiniMed violated Puerto Rico's Assistive Technology Equipment Guarantee Act, Law No. 402 of September 9, 2000, P.R. Laws Ann. tit. 8 §§ 851-859 (2006).

Inasmuch as none of these allegations appear in the complaint we find plaintiffs are precluded from pursuing such causes of action in these proceedings.

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<sup>15</sup> Maria de los A. Rosa depo. Tr. 69.

<sup>16</sup> José E. Rodriguez depo. Tr. 11.

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**CONCLUSION**

Based on the foregoing, Medtronic MiniMed's Motion for Summary Judgment (docket No. **50**) is **DENIED**.<sup>17</sup>

IT IS SO ORDERED.

San Juan, Puerto Rico, this 6<sup>th</sup> day of May, 2008.

S/Raymond L. Acosta  
RAYMOND L. ACOSTA  
United States District Judge

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<sup>17</sup> See, Response in Opposition (docket No. **56**); Medtronic MiniMed's Reply (docket No. **63**) and Plaintiffs' Sur Reply (docket No. **73**).